K033822

TAB 3

FEB - 6 2004

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Official Contact

Zita A. Yurko
Manager, Regulatory Affairs/Product Assurance
Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668

724-387-4120
724-387-4206 (fax)
Email: Zita.Yurko@Respironics.com

Classification Reference 21 CFR 872.5570

Product Code LRK – Anti-Snoring Device

Common/Usual Name Oral Appliance

Proprietary Name Respironics Custom I Oral Appliance

Predicate Device(s) Respironics Silencer (K954530)

Reason for submission Modified design.

Substantial Equivalence

The modified device has the following similarities to the previously cleared predicate devices:

- ❑ Same intended use.
- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same manufacturing process.

Design verification tests were performed on the Respironics Custom I Oral Appliance as a result of the risk analysis and product requirements. All tests were verified to meet the required acceptance criteria. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the device described in this submission is substantially equivalent to the predicate devices.

The modified device complies with the "Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA," November 2002.

Intended Use

The Respironics Custom I Oral Appliance is intended for use by a dentist on adult patients as an aid for the reduction or elimination of snoring and obstructive sleep apnea.

Device Description

The Respironics Custom I Oral Appliance is a mandibular repositioner that is a removable dental device that is fitted in the patient's mouth that and is indicated to treat patients who snore and patients who have obstructive sleep apnea. The Custom I Device is fit by a trained dentist. The device is fit by boiling the device then custom fitting it into the patient mouth by biting on the device. Like its predicate, the Silencer (K95430), the Custom I Oral Appliance is intended to treat patients who snore and who have obstructive sleep apnea.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2004

Respironics, Incorporated
Mr. Zita A. Yurko
Manager, Regulatory Affairs
Home Care Division
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668-8550

Re: K033822
Trade/Device Name: Respironics Custom I Oral Appliance
Regulation Number: 872.5570
Regulation Name: Intraoral Devices For Snoring and Intraoral Deices For Snoring And Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: January 5, 2004
Received: January 7, 2004

Dear Mr. Yurko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033822

510(k) Number (if known): K033822

Device Name: Respironics Custom I Oral Appliance

Intended Use/Indications for Use

The Respironics Custom I Oral Appliance is intended for use by a dentist on adult patients as an aid for the reduction or elimination of snoring and obstructive sleep apnea.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033822